

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***  
**75279**

**DRAFT FINAL PRINTED LABELING**

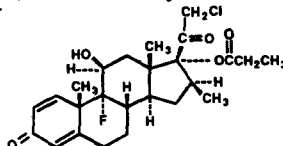
## Clobetasol Propionate Gel 0.05%

PK-2553-0  
000

### FOR TOPICAL USE ONLY.

**DESCRIPTION:** Clobetasol Propionate Gel 0.05% contains the active compound clobetasol propionate, a synthetic corticosteroid, for topical dermatologic use. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Chemically, clobetasol propionate is 21-Chloro-9-fluoro-11 $\beta$ ,17-dihydroxy-16 $\beta$ -methylpregna-1,4-diene-3,20-dione 17-propionate, and it has the following structural formula:



Clobetasol propionate has the molecular formula  $C_{28}H_{37}ClFO_6$  and a molecular weight of 466.98. It is a white to cream-colored crystalline powder insoluble in water.

Each gram, for topical administration, contains clobetasol propionate 0.5 mg in a base of propylene glycol, carbomer 934P, sodium hydroxide, and purified water.

**CLINICAL PHARMACOLOGY:** Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A<sub>2</sub> inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A<sub>2</sub>.

**Pharmacokinetics:** The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressing with hydrocortisone for up to 24 hours has not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin, while inflammation and/or other disease processes in the skin may increase percutaneous absorption. Greater absorption was observed for the clobetasol propionate gel formulation as compared to the cream formulation in *in vitro* human skin penetration studies.

Studies performed with clobetasol propionate gel indicate that it is in the super-high range of potency as compared with other topical corticosteroids.

**INDICATIONS AND USAGE:** Clobetasol propionate gel is a super-high potency corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Use in children under 12 years of age is not recommended.

**CONTRAINDICATIONS:** Clobetasol propionate gel is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

### PRECAUTIONS:

**General:** Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2 g per day.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy.

Patients receiving a large dose applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, a.m. plasma cortisol, and urinary free cortisol tests. Patients receiving super-potent corticosteroids should not be treated for more than 2 weeks at a time, and only small areas should be treated at any one time due to the increased risk of HPA suppression.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur that require supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Children may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (see PRECAUTIONS: Pediatric Use).

If irritation develops, clobetasol propionate gel should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing *failure to heal* rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of clobetasol propionate gel should be discontinued until the infection has been adequately controlled.

**Clobetasol propionate gel should not be used in the treatment of rosacea or perioral dermatitis, and should not be used on the face, groin, or axillae.**

**Information for Patients:** Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician.

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4. Patients should report any signs of local adverse reactions to the physician.

5. Patients should inform their physicians that they are using Clobetasol propionate gel if surgery is contemplated.

**Laboratory Tests:** The following tests may be helpful in evaluating patients for HPA axis suppression:

ACTH stimulation test  
A.M. plasma cortisol test  
Urinary free cortisol test

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Studies in the rat following oral administration at dosage levels up to 50 mg/kg per day revealed no significant effect on the males. The females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Clobetasol propionate was nonmutagenic in three different test systems: the Ames test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B WP2 fluctuation test.

**Pregnancy Teratogenic Effects: Pregnancy Category C:** Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

Clobetasol propionate has not been tested for teratogenicity by this route; however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent.

Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested down to 0.03 mg/kg. These doses are approximately 0.33 and 0.01 times, respectively, the human topical dose of clobetasol propionate gel. Abnormalities seen included cleft palate and skeletal abnormalities.

In rabbits, clobetasol propionate given by the same route was teratogenic at doses of 3 and 10 mcg/kg. These doses are approximately 0.001 and 0.003 times, respectively, the human topical dose of clobetasol propionate gel. Abnormalities seen included cleft palate, cranioschisis and other skeletal abnormalities.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. Clobetasol propionate gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when clobetasol propionate gel is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of clobetasol propionate gel in children and infants have not been established; therefore, use in children under 12 years of age is not recommended. Because of a higher ratio of skin surface area to body mass, children are at a greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids. They are therefore also at greater risk of glucocorticosteroid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children (see PRECAUTIONS).

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

**ADVERSE REACTIONS:** In a controlled trial with clobetasol propionate gel, the only reported adverse reaction that was considered to be drug related was a report of burning sensation (1.8% of treated patients).

In larger controlled clinical trials with other clobetasol propionate formulations, the most frequently reported adverse reactions have included burning, stinging, irritation, pruritis, erythema, folliculitis, cracking and fissuring of the skin, numbness of fingers, skin atrophy and telangiectasia (all less than 2%).

Cushing's syndrome has been reported in infants and adults as a result of prolonged use of topical clobetasol propionate formulations.

The following additional local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with super-high potency corticosteroids such as clobetasol propionate gel. These reactions are listed in approximate decreasing order of occurrence: dryness, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, irritation, striae, and miliaria.

**OVERDOSAGE:** Topically applied clobetasol propionate gel can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

**DOSAGE AND ADMINISTRATION:** Apply a thin layer of clobetasol propionate gel to the affected skin areas twice daily and rub in gently and completely (see INDICATIONS AND USAGE).

Clobetasol propionate gel is a super-high potency topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks, and amounts greater than 50 g per week should not be used.

As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Clobetasol propionate gel should not be used with occlusive dressings.

**HOW SUPPLIED:** Clobetasol Propionate Gel, 0.05% is supplied in 15 g, 30 g, and 60 g tubes.

Store between 15° and 30°C (59° and 86°F). Clobetasol Propionate Gel should not be refrigerated.

Rx only

Mfd. by: Taro Pharmaceuticals Inc., Bramalea, Ontario, Canada L6T 1C3  
Issued: June 1998

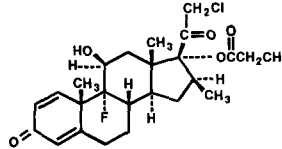
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MAY 28 1999

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured. Screw cap back on to reseal tube.

Mfg. by: Taro Pharmaceuticals Inc.  
Bramalea, Ontario, Canada L6T 1C3  
Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532  
TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.



15 g

NDC 51672-1294-1

## Clobetasol Propionate Gel, 0.05%

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Rx only

Keep this and all medication out of the reach of children.

**EACH GRAM CONTAINS:** Clobetasol propionate 0.5 mg in a gel base composed of propylene glycol, carbomer 934P, sodium hydroxide and purified water.

**USUAL DOSAGE:** Apply a thin layer of clobetasol propionate gel to the affected skin areas twice daily and rub in gently and completely.

See package insert for full prescribing information.

Store between 15° - 30°C (59° - 86°F). Do not refrigerate.

For lot number and expiry date see flap of carton or crimp of tube.

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Clobetasol  
Propionate  
Gel, 0.05%



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PK-2548-0  
M82



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3 51672 12942 2

30 g

NDC 51672-1294-2

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30 g

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Clobetasol  
Propionate  
Gel, 0.05%

TARO

TARO

PK-2550-0  
M267



May 28 1999

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3 51672 12943 9

60 g

NDC 51672-1294-3

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See package insert for full prescribing information.

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60 g

NDC 51672-1294-3

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Clobetasol  
Propionate  
Gel, 0.05%

**TARO**

**TARO**

PK-2552-0  
M930



179



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NDC 51672-1294-1

15 g

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15 g

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Gel, 0.05%**

**TARO**

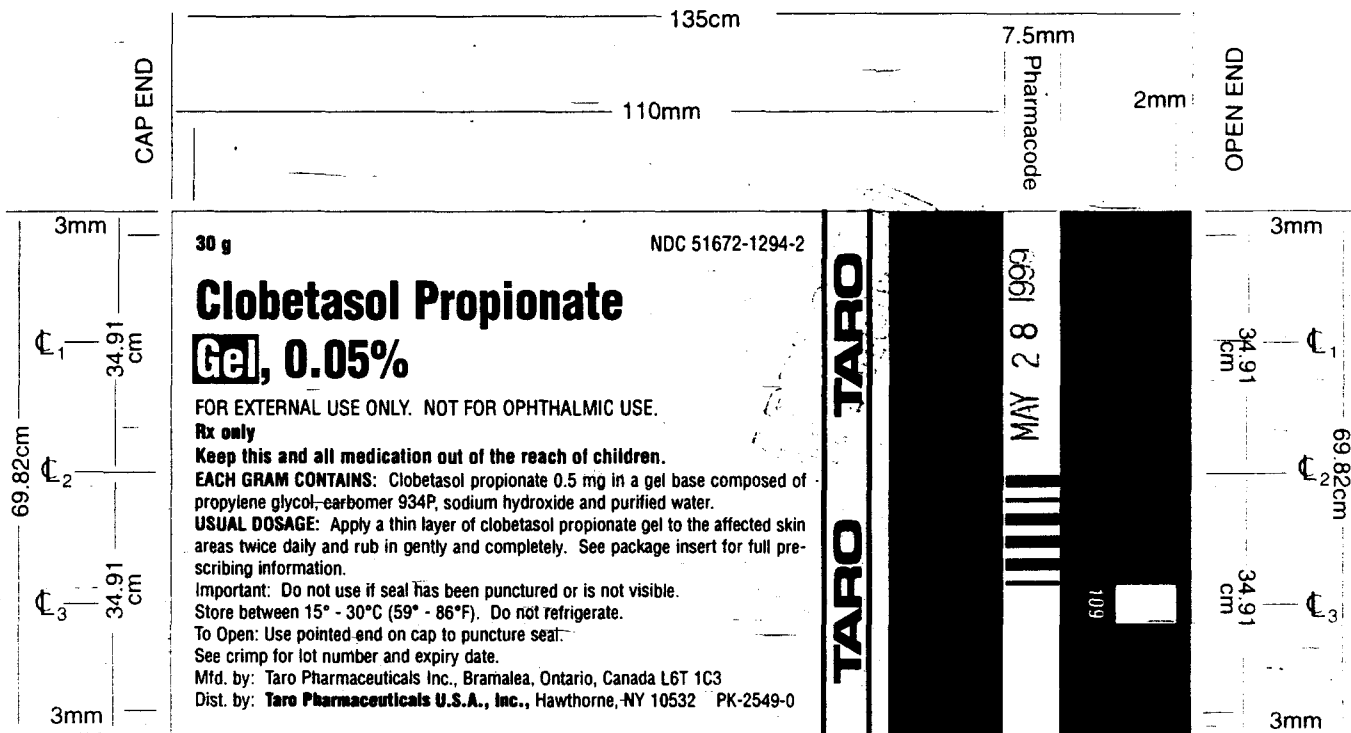
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PK-2548-0

M82





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3 51672 12942 2

30 g

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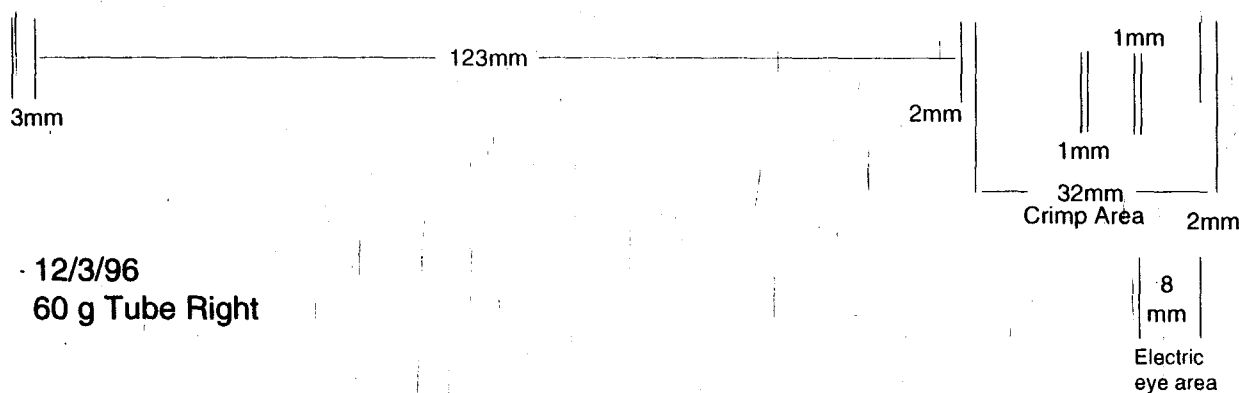
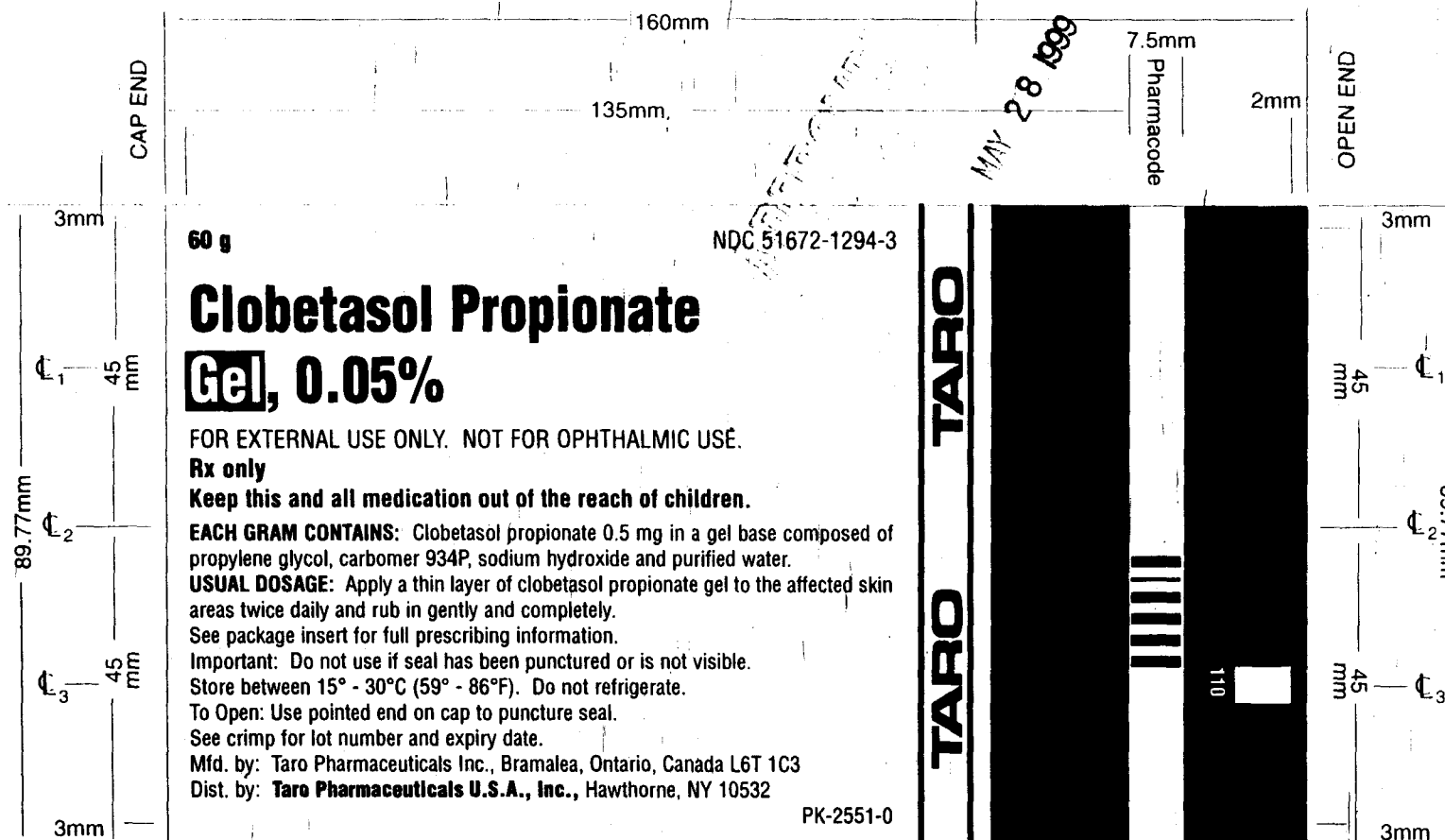
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Clobetasol  
Propionate  
Gel, 0.05%



PK-2550-0  
M267

MAY 28 1999



12/3/96  
60 g Tube Right

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3 51672 12943 9

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